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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,969	04/21/2000	Donald G. Wallace	17067-002040	6560

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EXAMINER
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ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/553,969	WALLACE ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,19-21 and 23-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 19-21 and 23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Reciept of response and declaration under 37 CFR 1.132 dated 7-5-07 is acknowledged.

Claims 1, 19-21 and 23-26 have been pending in the instant application.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 20, 21, 23, 25, 30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,818,517 to Kwee et al (Kwee).

Kwee et al discloses a pharmaceutical preparation comprising a hydrogel polymer and a drug, which is introduced by means of an injection syringe, which reads on the instant applicator having an extrusion orifice. Kwee teaches that the composition provides water necessary for the preparation of the highly viscous hydrogel that is already part of the total composition (col. 1). Thus, the composition of Kwee does not contain any free aqueous phase other than the water that forms a part of the hydrogel. Kwee teaches that the polymer has a swelling capacity but does not state the claimed percentages. However, Kwee teaches dextrin as a suitable polymer (examples), which is a polysaccharide and thus the swelling capacity is inherent to dextrin of Kwee et al. Further, the claimed property of in vivo degradation time being less than one year is inherent to the polymer because Kwee teaches the same class of polymer i.e., a polysaccharide.

2. Claims 19, 24, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee).

Instant claims are directed to protein and non-biological hydrogel and particle size of the hydrogel. While Kwee does not explicitly teach the claimed features, Kwee teaches a hydrogel polymer and suggests polymers such as dextran, starch, polyvinyl alcohol, etc (col. 2) are capable of swelling in water and homogenously injected out of the syringe without causing any practical problems and release the drug slowly over a period of time. Further, Kwee teaches that the polymer is in the form of dry particles (claims) and also suggests that the hydrogel can be used in combination with any drug such as locally active drugs, bactericidal, anti-inflammatories, etc. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use a particulate natural or synthetic (non-biological) polymer such as polyvinyl alcohol, having an appropriate particle size, as a hydrogel in combination with the any desired drug because Kwee suggests that the dry particulate polymer which has a capability to swell is useful in releasing the drug over a long period of time without having the conventional drawbacks such as water being separated from the hydrogel during injection at the site of interest.

3. Claims 26-29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee) in view of Berg et al.

Kwee fails to teach the claimed protein polymer, a clotting agent such as thrombin, or the claimed combination of polymers.

Berg teaches a collagen wound dressing material comprising resorbable collagen particles of 50 to 350 microns. Berg also teaches addition of several wound-healing agents such as growth factors, enzyme inhibitors, angiogenesis factors etc (col. 4). Berg teaches that collagen would dressings are capable of swelling at the desired ratios and still be injectable (examples 5 and 10). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ particulate collagen of Berg as a hydrogel in the teachings of Kwee and use the hydrogel alone or in combination with the hydrogels of Kwee for releasing drugs such as wound healing agents because Berg suggests that collagen dressings are capable of being resorbable, allow cellular in growth, and protect the wound to be treated while still permitting the required diffusion of gases and liquids.

The following rejections of record have been withdrawn:

Claim Rejections - 35 USC § 102

4. Claims 1, 19-21, 24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,424,208 to Wallace et al (Wallace).

Wallace discloses an injectable collagen implant material and a method of augmenting soft tissue comprising particles of crosslinked collagen and reconstituted fibrous collagen. Wallace particularly teaches the preparation of cross-linked gel particles, wherein a collagen gel is formed, followed by cross-linking. The cross-linked gel is then comminuted, fragmented or shredded by extruding through syringes (col. 4, L 40-68 and col. 5, L 1-9). Thus, the final hydrogel comprises a crosslinked gel and

fibrous gel, which meets the claim limitation "substantially free of free aqueous phase". The process of preparing the hydrogel described by Wallace includes the same process steps that are also described in the instant specification (page 34, example 9) and hence meets the limitation "single phase aqueous colloid". Further, because of the process being same, the claimed characteristics i.e., sub unit size, swell and degradation time are also inherent to the gels of Wallace.

5. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,424,208 to Wallace et al (Wallace), as applied to claims 1, 19-21, 24 and 28 above, and further in view of US 6,110,484 to Sierra.

Claim 34 is directed to a gelatin hydrogel composition. Wallace only teaches collagen hydrogels.

Sierra discloses a biomedical implant comprising a matrix material and a biodegradable porosifying agent, for a mechanically stable implant that allows for tissue and fluid influx into the matrix.

Sierra teaches collagen, gelatin, polyvinyl alcohol, polycarbonates etc., as suitable in the composition as biodegradable and biocompatible matrix and porosifying agents (col. 4). Sierra teaches that the above biodegradable matrix materials are suitable because they degrade a slower rate and also suitable for delivering therapeutic agents. Sierra further exemplifies hydrogels containing gelatin. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ gelatin or collagen as suitable hydrogels for tissue implantation or

wound healing because Sierra suggests both collagen and gelating gels as equivalent in wound healing or tissue remodeling. A skilled artisan would have expected to achieve the same dressing or remodeling tissue with either collagen or gelatin.

Response to Arguments

Applicant's arguments filed 7-5-07 have been fully considered but they are not persuasive.

Rejection under 102(b)-KWEE: Applicants argue that Kwee fails to teach a colloid free of aqueous phase and instead teaches hydrogel and therefore does not anticipate instant claims. However, the argument is not persuasive because instant specification describes that the claimed aqueous colloid is prepared by placing a non-crosslinked polymer such as gelatin in an aqueous buffer to form a hydrogel (see page 20, lines 21+. Thus, the hydrogel of instant and that of Kwee are not different. It is argued that Kwee does not disclose the disintegration rate. However, the burden is on applicants to show that the reference product does not possess the claimed disintegration rate, which applicants failed to show. The argument that the Kwee patent is brief and provide limited description is not persuasive because even if prior art, teaches one embodiment or description that meet the instant claim, the prior art still anticipates the instant claimed invention. With respect to the detailed argument separate phases on page 6 of the response, examiner refers to previous action where this argument has been addressed. Further, as explained the hydrogel according to

instant invention comprises a single-phase colloid and the definition allows for the thickening agent of Kwee, which prevents the presence of any free aqueous phase.

In this regard, the declaration submitted by Edward Osawa has been fully considered and not found persuasive. Kwee teaches that the thickening (water-soluble) agent is added to prevent the separation of water that is left after the insoluble polymer is swelled, thus suggesting that when the polymer is swollen to hydrogel, there is no free aqueous phase available. The instant claim language does not exclude the presence of the thickening agent because the agent is not part of the swollen polymer and is distinct. Hence the swellable polymer of Kwee still forms a single phase.

Applicants' argument that even the presence of a thickener does not negate the presence of a free aqueous phase is not persuasive because applicants have not provided any evidence showing the same and the presence of the free aqueous phase is not a function of the solubility of the water-soluble polymer but also depends on the free water available and the amount of the polymer. Therefore, absent any evidence, the argument is not persuasive.

Rejection under 35 USC 103(a) –KWEE alone or KWEE in view of BERG: Applicants argue that Kwee fails to teach the limitations of independent claim1 and therefore the claims 19, 24,31 and 32 that directly depend from claim 1 are allowable based on the allowability of claim 1. Similarly, applicants argue that claims 26-29 are allowable because claim 1 is allowable. However, applicants' arguments are not persuasive because the arguments regarding the teachings of Kwee have been

addressed before and applicants have not provided any evidence to show that the polymer of Kwee does not possess the above properties.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
September 28, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER